# In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 23-630V

UNPUBLISHED

TESSA NEEDHAM,

Petitioner.

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: December 20, 2023

Andrew D. Downing, Downing, Allison & Jorgenson, Phoenix, AZ, for Petitioner. Julia M. Collison, U.S. Department of Justice, Washington, DC, for Respondent.

#### **DECISION**<sup>1</sup>

On May 2, 2023, Tessa Needham filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa—10 through 34<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that she suffered various injuries due to receipt of doses of the human papillomavirus ("HPV") vaccine on December 16, 2014, February 17, 2015, and July 14, 2015. ECF No. 1 at 2.

Because the petition was untimely filed, and Petitioner has failed to establish a basis for equitable tolling, this case is **DISMISSED**.

#### **Relevant Factual Background**

On December 16, 2014, at the age of ten, Petitioner went with her mother to a well-child visit where she received the first dose of HPV vaccine at PeaceHealth. Exhibit 12 at 6; Exhibit 6 at 8 (vaccination history). Petitioner's mother completed the medical forms for

<sup>&</sup>lt;sup>1</sup> Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <a href="https://www.govinfo.gov/app/collection/uscourts/national/cofc">https://www.govinfo.gov/app/collection/uscourts/national/cofc</a>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "Sec." references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Petitioner and provided a medical history to the doctor. Exhibit 12 at 3-10. The record for this appointment noted "Immunizations today: per orders. Risks and benefits briefly reviewed for each component of each vaccine. Vaccine counseling provided and vaccine CDC handouts given." *Id.* at 6. The administration records for the second and third vaccinations, however, were not contained in PeaceHealth medical records or in the records of any other providers. Thus, a summary vaccination history is the only documentation that Petitioner also received the second and third doses. Exhibit 6 at 8.

Thereafter (Petitioner alleges), beginning in the fall of 2015 Petitioner began to experience more frequent headaches, diminished energy, lightheadedness, muscle weakness, memory issues, and difficulty concentrating. ECF No. 1 ¶ 5. Petitioner then developed additional symptoms, and was later diagnosed with postural orthostatic tachycardia syndrome, or "POTS." *Id.* ¶ 18.

Facially, Petitioner's claim herein was filed over *seven* years after her last HPV dose, which was administered in July 2015, and seven-plus years from the time she began manifesting symptoms. But Petitioner maintains her delay is excusable. Thus, in an affidavit dated April 26, 2023, Petitioner has attested that at the time these vaccinations occurred, no Vaccine Information Statements (VIS) were provided, and no information was relayed about the Vaccine Program. Exhibit 1 ¶ 2. Petitioner only learned that the HPV vaccine might be capable of causing adverse effects in April 2023, but then immediately contacted an attorney thereafter. Exhibit 14 ¶¶ 5, 6. Petitioner did not submit an affidavit from her mother, who was thirty-seven years old at the time of the vaccinations, about whether any counseling or information was provided about the HPV vaccine. Exhibit 12 at 8.

## **Relevant Procedural History**

Given that the timeliness of the claim was legitimately called into question merely by the face of the actual Petition, while the case was still in the initial "pre-assignment review" (a process utilized by the Office of Special Masters to assess whether a claim's primary evidentiary documentation has been filed), I ordered Petitioner to show cause why the claim had not been filed outside the Act's 36-month statute of limitations. Sec. 16(a)(2); ECF No. 14.

On November 28, 2023, Petitioner filed a response. ECF No. 16. Petitioner did not dispute the onset of symptoms in 2015, or that her petition was filed in 2023 (and not sooner than the fall of 2018), but instead argued that the limitations period should be equitably tolled. Petitioner asserted that she had diligently pursued her rights once she reached the age of majority, realized the connection between her injuries and the HPV vaccine, and became aware of her legal rights. Petitioner also made allegations not relevant to a Vaccine Act claim, about the perfidious conduct of the vaccine manufacturer

in fraudulently concealing the HPV vaccine's harmful character from the public. ECF No. 16 at 21. Relatedly, Petitioner argued that the failure of a healthcare professional to provide her with a VIS at the time of vaccination can be attributed to the Department of Health and Human Services' failure to systematically ensure that VIS are explained and provided to all vaccine recipients. *Id.* at 11.

On December 1, 2023, Respondent submitted a responsive brief of his own, arguing for dismissal due to untimeliness. ECF No. 18. Respondent maintained that Petitioner in fact had not diligently pursued her rights before filing a vaccine claim in 2023, but did not address Petitioner's argument that Petitioner's status as a minor was relevant to the diligence inquiry. Respondent also disputed the veracity of contentions about the manufacturer's conduct, and whether it could in any event constitute an extraordinary circumstance that would serve as a basis for tolling of the statute.

On December 14, 2023, Petitioner filed a reply to Respondent's arguments. ECF No. 19. That document reiterated Petitioner's prior arguments.

#### **Legal Standards**

The Vaccine Act's statute of limitations is thirty-six months. Sec. 16(a)(2). The statute begins to run from the manifestation of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis (or even recognized by a claimant as significant). *Id.*; *Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013).

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act's statute of limitations. See Cloer v. Sec'y of Health & Hum. Servs., 654 F.3d 1322, 1340-41 (Fed. Cir. 2011). However, in keeping with applicable U.S. Supreme Court precedent, equitable tolling of a limitations period is to be permitted "sparingly." Irwin v. Dep't of Veterans Affairs, 498 U.S. 89, 96, (1990). The appropriateness of equitable tolling is ultimately to be determined on a case-by-case basis, without rigid application of any relevant overarching guidelines. Holland v. Florida, 560 U.S. 631, 649–50 (2010); accord Arctic Slope Native Ass'n v. Sebelius, 699 F.3d 1289, 1295 (Fed. Cir. 2012).

Petitioners must prove two elements to establish equitable tolling: (1) that petitioner diligently pursued her rights, and (2) an extraordinary circumstance prevented her from timely filing the claim. *K.G. v. Sec'y of Health & Hum. Servs.*, 951 F.3d 1374, 1379 (Fed. Cir. 2020) (citing *Menominee Indian Tribe v. United States*, 577 U.S. 250, 255 (2016)).

When first articulating this limited exception to equitable tolling, the Federal Circuit primarily enumerated fraud and duress—but not, for example, *lack of awareness* on a

petitioner's part that she might have an actionable claim. *Cloer*, 654 F.3d at 1344–45 (noting that tolling of the Vaccine Act's statute of limitations period is not triggered "due to unawareness of a causal link between an injury and administration of a vaccine"). More recently, in *K.G*, 951 F.3d at 1380–82 (Fed. Cir. 2020), the Circuit more explicitly endorsed the proposition that an individual's demonstrated mental incapacity is a basis for equitable tolling in the Program. For a mentally incapacitated individual, the Circuit instructed that the details of the individual's legal guardian would affect whether there was reasonable diligence. *K.G*, 951 F.3d at 1382 (Fed. Cir. 2020).

#### **Analysis**

The untimeliness of this filing is acknowledged by Petitioner, so the only question to be resolved is whether equitable tolling should save the claim. But Petitioner has failed to establish both elements of equitable tolling – diligent pursuit and extraordinary circumstances.

## A) Diligent pursuit

Petitioner argues that her diligent pursuit of her vaccine claim was impeded by her minor status at the time of the vaccine dose's administration. Once she turned eighteen years old in 2022, however, she thereafter began to diligently pursue her claim – after she learned in 2023 that the HPV vaccine had potential adverse effects.

These arguments are wholly unpersuasive. It is beyond question that claims asserted in the Vaccine Program are not subject to a "discovery rule," accruing only when a claimant *learns* he or she might possess a cause of action. Rather, the statute of limitations period is triggered by the onset of Petitioner's symptoms – whether or not onset was understood to be the start of the claimed injurious illness or condition. *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc). And the failure to be advised of the Vaccine Program or the Act does not support equitable tolling of the statute of limitations period for an otherwise-untimely filed petition. *Speights v. Sec'y of Health & Hum. Servs.*, No. 03-2619V, 2013 WL 5944084, at \*13 (Fed. Cl. Spec. Mstr. Oct. 17, 2013). Thus, a petitioner cannot generally shield an untimely claim from dismissal by asserting, even in good faith, that she literally was unaware of her Vaccine Act "rights."

Petitioner attempts to leverage her minor status at the time of vaccination into an exception to the above. But the Vaccine Act does not provide for tolling of claims involving minors simply due to their age, nor does it treat minors as "mentally incapacitated" for purposes of the Act's statute of limitations. The only savings clause in the Act is for revisions to the Vaccine Injury Table, which allow an otherwise untimely claim for newly added vaccines to be filed. Sec. 16(b). And there is no argument here that a Table claim

specifically involving the HPV vaccine was added that would cover Petitioner's delayed filing.<sup>3</sup>

As a result, Petitioner's personal diligence herein once she learned of the claim's potentiality in 2022 is almost beside the point. Since the Act permits claims to be brought by a minor's parent or legal guardian, it is *that* person's diligence that bears on this aspect of the tolling question. And parents are generally presumed to be adequate surrogates for their children. *United States v. Alvarez*, 710 F.3d 565, 568 n.10 (5th Cir. 2013); Court of Federal Claims Rule 17(c)(1)(A)(guardian permitted to sue on behalf of a minor); Vaccine Rule 2(c)(2)(C) (parents are presumed to be able file in a representative capacity on behalf of their children without supporting documentation).

At best, the Federal Circuit has noted that a guardian's effectiveness in acting on behalf of a legally incapacitated individual should be assessed on a case-by-case basis, and there thus could be circumstances where the adequacy of a guardian's performance of their duties bears on tolling. K.G, 951 F.3d at 1382 (Fed. Cir. 2020). But Petitioner has made no showing at all that her mother (or some other legal guardian, for that matter) could not have brought the claim, or acted diligently in the face of its delayed prosecution. As noted above, Petitioner's mother was present when the first HPV vaccine dose was administered in December 2014, and presumably would attend most of Petitioner's other appointments at her young age. Petitioner's mother would also be the person to consent to medical treatment, including vaccinations, for her daughter, and the person to receive all medical information, including a VIS. Petitioner has not submitted an affidavit from her mother to state whether her mother understood the risks of the HPV vaccine, whether her mother received the VIS, whether her mother diligently pursued Petitioner's vaccine claim, whether her mother chose not to file a vaccine claim, or whether her mother believed that extraordinary circumstances prevented the filing of a vaccine claim. Thus, there is no evidence herein suggesting that Petitioner's mother's diligence is in question.

## B) Extraordinary Circumstances

Petitioner's arguments about the purported fraudulent conduct of the vaccine's manufacturer, in hiding proof of the vaccine's dangers, deserve even less consideration. ECF No. 16 at 21. As a threshold matter, these contentions are speculative and not evidentiarily-supported. And regardless of their actual truth, the fact remains that the Government has approved the HPV vaccine for administration to minors, rendering it "covered" under the Act. The only issue to be resolved in a Program case is whether

of this claim.

<sup>&</sup>lt;sup>3</sup> In fact, the HPV vaccine was added to the Table in 2007 – *eight* years before onset is alleged herein to have occurred. 42 C.F.R. § 100.3 (Vaccine Injury Table); National Vaccine Injury Compensation Program: Addition of Meningococcal and Human Papillomavirus (HPV) Vaccines to the Vaccine Injury Table, 72 Fed. Reg. 19937 (Apr. 20, 2007). The Act's lookback provisions have no relevance at all to the timeliness

(assuming, as here, the claim is not a Table claim) the claim meets the standards for causation – and those standards have nothing to do with a manufacturer's alleged misconduct in preparation or promotion of the underlying vaccine.

These allegations also are not a basis for tolling under the circumstances. Petitioner simply has not shown that contentions of corporate misconduct not specific to, or directed at, her personally could rise to the level of the kind of "fraud" that might excuse failing to file a Program claim in a timely manner. Nor has she persuasively established that the vaccine administrator's "failure to warn," or provide a VIS in 2015, is an extraordinary circumstance. Even assuming the factual accuracy of that allegation, it remains the case (as the Circuit recognized in *Cloer*) that vaccine claims accrue upon onset – and that the failure to be advised of the Vaccine Program does not support equitable tolling. *Cloer*, 654 F.3d at 1340; see also Speights, 2013 WL 5944084, at \*13. And arguments about governmental agency knowledge of a failure to warn reflect overheated, almost-conspiratorial allegations that do not come close to excusing the claim's untimely nature.

Finally, Petitioner also asserts that the safety of the HPV vaccine is "heavily disputed and should not be resolved on these papers alone." ECF No. 19 at 7. But this argument willfully ignores the extent to which I have personally ruled in numerous prior cases that medical science does not preponderantly support the contention that the HPV vaccine can cause POTS. See, e.g., Hughes v. Sec'y of Health & Hum. Servs., No. 16-930V, 2021 WL 839092, at \*31 (Fed. Cl. Spec. Mstr. Jan. 4, 2021), mot. for review denied, 154 Fed. Cl. 640 (2021); E.S. v. Sec'y of Health & Hum. Servs., No. 17-480V, 2020 WL 9076620, at \*40, 43 (Fed. Cl. Spec. Mstr. Nov. 13, 2020), mot. for review denied, 154 Fed. Cl. 149 (2021); McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at \*44-45 (Fed. Cl. Spec. Mstr. July 15, 2019). Indeed - present counsel litigated many of these claims himself. The Act does not require that the same theory rejected so many times before must be relitigated by the Program ad infinitum (especially in the absence of new compelling evidence). Rather, special masters are expressly empowered to rely on their expertise, earned in adjudicating Program cases, in subsequent similar matters. To suggest that they should ignore what they have learned in that process reveals a complete miscomprehension of the Program's underlying goals and purposes.

<sup>&</sup>lt;sup>4</sup> In an affidavit dated April 26, 2023, Petitioner attested that eight years ago, when she was ten years old, she did not receive a VIS following the HPV vaccinations or any information about the Vaccine Program. Exhibit 1 ¶ 2. But the contemporaneous medical records for the first vaccination on December 16, 2014, actually support the conclusion that Petitioner's mother likely received guidance about HPV vaccine and a VIS. Exhibit 12 at 6.

## Conclusion

Thus, Petitioner has failed to establish equitable tolling. This case is dismissed for being untimely filed. The Clerk of Court shall enter judgment accordingly.<sup>5</sup>

IT IS SO ORDERED.

<u>s/Brian H. Corcoran</u> Brian H. Corcoran Chief Special Master

<sup>&</sup>lt;sup>5</sup> If Petitioner wishes to bring a civil action, she must file a notice of election rejecting the judgment pursuant to § 21(a) "not later than 90 days after the date of the court's final judgment."